



USDA Foreign Agricultural Service

# GAIN Report

Global Agriculture Information Network

Template Version 2.09

Voluntary Report - public distribution

**Date:** 7/16/2007

**GAIN Report Number:** CH7058

## China, Peoples Republic of

### Agricultural Situation

### The 11th Five-Year Plan on Food and Drug Safety

### 2007

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**Report Highlights:**

This is an UNOFFICIAL translation of the 11th Five-Year Plan on Food and Drug Safety as published by the State Council of China. The plan outlines targets for the administration and surveillance of food and drug safety in 2006-2010.

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Includes PSD Changes: No  
Includes Trade Matrix: No  
Unscheduled Report  
Beijing [CH1]  
[CH]

**Executive summary**

The State Council of China published the 11<sup>th</sup> Five-Year Plan on Food and Drug Safety in April 2007. In an effort to step up supervision and administration on the safety of food, drug and food-service industries, the plan outlines the targets and major tasks for the government during the period from 2006-2010.

Special thanks go to the Embassies of Argentina, Brazil, and Canada in China for their assistance in translating this document.

BEGIN TRANSLATION

**The Eleventh Five-Year National Plan for Food and Drug Safety**

In order to further strengthen the supervision on food, drugs and hygiene of food and beverage services, to constantly enhance the safety of food, beverage and drug use for the public and to promote social harmony and stability, this Plan is formulated in accordance with the "Outline of the 11th Five-Year Plan for National Economic and Social Development of the People's Republic of China" and the relevant guidelines and policies of the Communist Party of China (CPC) Central Committee and the State Council.

**Part One Guiding Thoughts and Basic Principles****I. Guiding Thoughts**

Guided by Deng Xiaoping's theory and the important thoughts of the "Three Representatives", to earnestly implement the scientific concept of development, fully perform the government duties in social administration and public service, strengthen facility construction for the supervision on food and drugs, improve the technical standard system, vigorously uplift the technical level of inspection and testing, innovate the supervision mechanism, standardize supervisory behavior, enhance the capability and level of supervision, safeguard the safety of food, beverage and drug use for the public, and make due contribution to building a well-off society in a comprehensive way and constructing a harmonious socialist society.

**II. Basic Principles**

Firstly, we shall adhere to the people-based principle, in order to serve the overall interests of the country. We must take the protection of the safety of food, beverage and drug use for the public as the starting point and the end result of all our work, and ensure that the supervision on food and drug safety is compatible with the economic and social development, with the overall goal of building a well-off society in a comprehensive way, and with the structural reform of the national administrative management system.

Secondly, we shall adhere to scientific supervision and innovative mechanism. We must establish the concept of scientific supervision, improve the supporting technology system, enhance the capability and level of supervision on food and drug safety, innovate the supervision system and build a new supervision mechanism that suits the national conditions and meets the requirements of a socialist market economy system.

Thirdly, we shall adhere to full-process supervision and administration according to law. We must strengthen food and drug safety supervision in accordance with law, continuously improve the laws and regulations pertaining to food and drug safety supervision, ensure stringent law enforcement, standardize supervisory behavior, and achieve the full-process of standardized and effective supervision on all aspects relating to food and drugs.

Fourthly, we shall adhere to an all-round, well-coordinated approach and integrated resource management. We must aim to take full advantage of the available resources, optimize resource deployment, bring into full play the functions of each area and aspect in food and drug safety supervision, establish a food and drug safety supervision mechanism

demonstrating coordinated efforts of joint administration, and utilize effective resources to maximize efficiency.

Fifthly, we shall adhere to strengthening grass-root and basic-level supervision. We must take grass-root and basic-level supervision on food and drug safety as a high priority, organize and mobilize sufficient financial, technical and human resources to better equip grass-root and basic-level units, and considerably reinforce grass-root development and basic work on food and drug safety supervision.

## **Part Two Development Objectives**

Through efforts made over an estimated period of five years, the food and drug supervision system and mechanism will be gradually improved; the law and regulatory system will become more perfect; the quality of supervisory forces will be improved; the capability to exercise administration according to law will be further enhanced; infrastructure construction will be strengthened; technical equipment will be further upgraded; the development of food and drug safety standards and the level of testing technology will be notably advanced; the manufacturing and distribution of food and drugs shall be conducted in a markedly improved and more orderly manner; illegal and criminal activities in manufacturing and distributing fake and inferior food and drugs will be effectively curbed; and the number of food and drug safety incidents will be significantly reduced.

### **I. By the end of the 11th Five-Year Plan period, a safeguard system for food safety to be basically established**

- The food safety information monitoring network will cover 90% of the country;
- The quality safety qualification rate of fresh/live agricultural products in whole-sale markets, large-scale farmers' trading markets and chained supermarkets in large and medium-sized cities will reach 95% based on spot checks;
- 100% of major food safety incidents will be dealt with;
- The food recall system will cover 80% of the country;
- National specific inspections on food manufacturers will cover 90% of the country

### **II. By the end of the 11th Five-Year Plan period, the level of drug supervision to be substantially upgraded**

- The rural drug supervision network will attain a 100% coverage rate, and that of the rural drug supply network will remain at 80% or above;
- In terms of independent capabilities to carry out full-scope inspections against the existing national drug standards, the drug inspection institutes at the provincial and port levels will have the capability to conduct 100% of such inspections, while the drug inspection institutes at the municipal (prefecture) level will have the capability for 80%;
- The state-level medical devices inspection institutes will have the capability to inspect 100% of the products under their jurisdiction, while provincial medical devices inspection institutes will have the capability to inspect over 95% of conventional products in the market;
- The coverage rate of drug supervision spot inspections will be increased from the current 30% to 80%.

## **Part Three Major Tasks**

### **I. Food Safety**

#### **1. To strengthen food safety monitoring**

Regionalize the production areas of edible agriculture products. Establish environmental safety monitoring systems for the production areas of agricultural products, to systematically

investigate pollution in the production areas and carry out environmental and quality safety monitoring on key regions and production areas of representative agricultural products. Strengthen the quality and environmental safety management of agricultural inputs. Establish a national system of monitoring and control on pesticide and veterinary drug residues, and expand the network of routine monitoring of quality and safety of agricultural products from coverage of the current 37 cities to all the large and medium-sized cities across the country. Establish a system of monitoring and control on the pollution of raw grain, monitor the quality, safety and hygiene of raw grain and build a network of monitoring of the grain quality and safety and the hygiene of raw grain. Carry out risk monitoring on non-food raw materials, systematically investigate pollution of non-food raw materials, establish a national special inspection system on compulsory standards of key food, implement an electronic labelling management system, and establish and standardize a food recall supervision and management system. Improve the spot check and routine monitoring system for food safety, hygiene and quality, set up food quality monitoring and direct-reporting points. Improve the national monitoring network on food contaminants and food borne diseases.

### **Column 1: Food Safety Monitoring**

#### **Environmental monitoring and control**

Reinforce the environmental monitoring and control of the “vegetable basket” production bases in key cities across the country, carry forward environmental safety regionalization and monitoring of key pollution sources in the production areas of agricultural products around Bohai Region, Pearl River Delta and Changjiang River Delta. Establish monitoring points interlinked through network to survey the environment in the production areas of agricultural products in key cities, build a data sharing platform on environmental quality in the production areas of agricultural products across the country.

#### **Market quality monitoring and control**

Improve the routine market monitoring system, and establish monitoring and control points to survey the quality of fresh/live agriculture products in wholesale markets, large-scale farmers’ trading markets and chain supermarkets in large and medium-sized cities.

#### **Food contaminants and food borne diseases monitoring**

Improve the food contaminants and food borne diseases monitoring network, which consists of provinces (regions, municipalities) as the monitoring and control units down to cities and counties as the monitoring points.

#### **Construction of bases**

Establish agricultural products and food demonstration bases under the circular economy model; accelerate the construction of bases for pollution-free food (agricultural products), good agricultural practice (GAP), green food and organic food.

#### **Non-food raw material monitoring and food recall**

Improve the pollution monitoring network on non-food raw materials at three levels – provincial, municipal and county level; carry out risk monitoring of non-food raw materials in key regions, of key products and key substances. Implement food recall work for high-risk food products such as meat products, dairy products, beverage, processed grain products, and edible vegetable oil.

## **2. To upgrade the level of food safety inspection and testing**

Integrate and take full advantage of the available food inspection and testing resources, tighten up laboratory qualification management, preliminarily establish a coordinated, consistent and effective operational food safety inspection and testing system, achieve the sharing of testing resources, meet the demands for safety supervision on the full process of food production, distribution and consumption, strive to bring the technology of the state-level food safety testing institutes up to par with advanced international level. Promote the socialization of inspection and testing institutes, and vigorously encourage and develop third-party testing institutes.

**Column 2: Key Aspects in Building Food Safety Testing Capacity****Inspection and testing on the quality and safety of agricultural products**

On the basis of an integration of available resources, establish state-level centres of research on quality standard and testing technology for agricultural products, specialized quality inspection centres for agricultural products, regional quality inspection centres, provincial integrative quality inspection centres for agricultural products and county-level testing stations for agricultural products.

**Food quality and safety testing**

Enhance the capacity building for state-level food quality supervision and inspection centers and municipal/county-level product quality inspection institutes to carry out food quality and safety testing.

**Testing on food contaminants and food borne diseases**

Promote testing technology against common hazard elements in the food and beverage industry; improve rapid testing technology against 10 types of common chemical and biological contaminant elements in the food and beverage industry.

**Rapid testing**

Depending on needs, gradually equip food safety supervision and administrative departments with necessary rapid testing facilities and rapid testing vehicles.

**3. To improve standards pertaining to food safety**

Further strengthen the efforts in formulating and revising food safety standards and basically establish a unified and scientific food safety standard system. Advance the process of adopting international and foreign advanced standards into China's food safety standards, and actively participate in the formulation and revision of international standards. Formulate feasible transitional or classification standards in accordance with China's specific conditions associated with food production, processing and distribution.

**Column 3: Key Aspects in the Formulation of Standards Pertaining to Food Safety****Environmental pollution control standards**

Formulate environmental pollution control standards targeting mainly at the environment of the production areas of grain crops, vegetable, animal and aquatic products.

**Standards pertaining to food safety**

Formulate the production area environmental standards required for certification and surveillance of pollution-free products, good agricultural practice (GAP), organic and green food, standards for grain and major agricultural products, rational standards on the use of pesticides and chemical fertilizers, GM biological safety standards, and standards for prevention and control of animal diseases; complete the formulation and revision of about 500 standards concerning residues and inspection methods of pesticides, veterinary drugs and toxic heavy metal elements; complete the formulation and revision of standards concerning residues and inspection methods of biological toxin and harmful micro-organisms; complete the formulation and revision of the hygiene standards for nutrition labeling, food containers and packaging materials, basic hygiene standards and inspection methods for food contaminants, and hygiene standards for food products and hygiene standards for the use of food additives; formulate standards concerning storage, transport and circulation safety such as the temperature and operational rules on cold chain logistics for fresh/live food.

**Demonstration of standardization**

Build a demonstration system of quality and safety standardization for bulk fresh/live agricultural products, superior agricultural products and agricultural products for export, and establish state-level agricultural standardization demonstration parks.

**4. To build a food safety information system**

Take full advantage of the available information sources and infrastructure, build a national food safety information platform and form a food safety information network composed of the following four levels – national, provincial, city and county level, as well as a national direct-reporting network targeting at food safety elements of the key enterprises; build a food safety dynamic information database with high capacity, manageability and enhanced security; establish a national food safety basic information sharing system and create a coordinated network working environment serving for food safety monitoring and analysis, information notification, contingency early warning, emergency response, scientific research on food safety as well as providing social and public service. Accelerate the establishment of a unified food safety public notification system.

**Column 4: Key Projects in Systematizing Food Safety Information****Food safety information monitoring network**

Build and improve the food safety information-monitoring network, and gradually form a unified and scientific food safety information evaluation and early warning system.

**Electronic surveillance**

Gradually build an electronic surveillance network to monitor food production, processing and distribution, and achieve electronic surveillance of food production and processing, qualification of operating businesses and product quality.

**Food safety information centre**

Based on the food safety information network and the integration of the available resources, build a food safety information centre to classify, filter, comprehensively analyze and monitor food safety information, make assessments on the food safety situation and perform early warning.

**5. Enhance the science and technology supporting capability for food safety**

Carry out basic research, high-tech research, establish key technology research on food safety and a platform for sharing food safety research statistics, and strengthen research of application technology and relevant strategies. Monitor standards of Codex Alimentarius Commission, supervision measures on food safety of major trading countries, and evaluation announcements of WTO's Agreement on the Application of Sanitary and Phytosanitary Measures and Agreement on Technical Barriers to Trade. Strengthen capacity building of food safety technology, and set up preliminarily an open food safety research system, which has autonomous and innovative capability and is internationally compatible. Enhance quality team building and subject building of food safety.

**Column 5: Key Points in Food Safety Scientific Research****Monitoring research**

Including Codex Alimentarius Commission, and food safety management system, policies, laws and regulations, standards, safety guarantee techniques, key testing methods of major trading countries.

**Research of evaluation technology**

Involving novel material for food, novel technology and genetically modified foods, food additives and food contact materials.

**Research of risk assessment technology**

Involving pathogenic microorganisms, pesticide and veterinary drug residue, novel foods, chemical (including biological toxins) hazardous material; set up hazard assessment model and methods for food-borne hazards; put forward high-risk food lists and hazard control measures.

**Research of application technology**

Including tracing technique for characteristics of food varieties, mapping technique for food production areas, labelling of food production areas and bar coding tracing technique, quality safety tracing technique for agricultural products, and inspection and testing technique, testing methods in food processing and distribution, testing methods of producing and selling forged products, quick testing of food safety, laboratory confirmation technique, standardization of testing methods and safety certification, early warning of food safety emergencies, and food safety control measures and research in food production, processing



and transportation.

## **6. Strengthen the building of emergency response system for food safety emergencies and major incidents**

Improve emergency response system of food safety, and set up food safety quick response connecting mechanism. Improve emergency direction and decision-making system, emergency surveillance, reporting and early warning system, technical supporting system for emergency testing, system for emergency response team and material assurance, and improve the bases for training and exercises, establish on site treatment capability, and enhance government emergency treatment capability. Enhance comprehensively the supervision of investigation on major food safety incidents, improve punishment system, set up system for the return visits by emergency supervisors and gradually complete a national system of specialized food safety supervisors.

### **Column 6: Key Points in Building A Food Safety Emergency Response System**

#### **Emergency response and treatment**

Gradually establish a coordinated network and platform for food safety emergencies and major incidents, strengthen the building of a direction and decision-making system.

#### **Quick response of food poisoning**

Establish a reporting and response system in restaurant industry regarding food poisoning. Improve capability of treatment and tracing of food poison sources.

#### **Quick response in food processing, distribution**

Establish emergency response and treatment system in food processing and distribution.

## **7. Establish food safety evaluation and assessment system**

Establish risk analysis and evaluation system, investigate potential threats of foods and consequences and possibilities of danger, and rank the risk of foods accordingly. The result of risk assessment is provided as the basis for government to make decision and management for food safety.

### **Column 7: Food Safety Evaluation and Assessment System**

#### **Investigation and evaluation**

Investigate and evaluate the establishment and implementation of food safety system by enterprises, as well as the safety of livestock, vegetables and fruits, aquatic products, alcoholic products, dairy products, baby products, grain and oil and their products, seasoning, instant food, bean-made products, drinking water, food additives and food packaging materials.

#### **Risk assessment**

Conduct food safety risk assessment on pesticide and veterinary drug residues, contamination of harmful and noxious substances, food additives, food packaging materials, food processing techniques and facilities.

#### **Special inspection of key foods**

Launch nationwide inspection of 15 key categories of food, and annual compulsory inspection on production and processing enterprises.



## 8. Improve food safety credibility system

Improve public awareness of credibility, build up an environment of credibility and develop a culture of credibility. Establish preliminarily a system to utilize food safety credibility, comprehensively promote food safety credibility system in its ability to regulate, guide and supervise food safety work. Gradually establish food safety credibility records of enterprises and execute supervision by categorization of food safety credibility. Improve the system of "local governments bare the full responsibility for food safety work, enterprises are the first responsible parties for food safety", enhance self-discipline of enterprises and establish red and black list of enterprises.

### Column 8: Food Safety Credibility

#### Supervision by categorization of food safety credibility

Establish information system for registration records of main food production trading enterprises, and categorization database for main food producers and traders, collect widely access information of main food producers and traders, food safety supervision information, consumer complaint and report information, improve a credibility categorization supervisory system for main food producers and traders

#### Quantitative classification management

Carry out quantitative classification management of food inspection and strengthen health certification and supervision of food sanitation.

## 9. Carry on special campaigns on food safety

Severely crack down forgery of food production and trade, prioritize crackdown on high safety risk foods. Improve food safety level of production, processing, transportation and consumption of grain, meat, vegetables, fruits, dairy products, bean products and aquatic products which are closely related to people's daily life. Improve regional food safety supervision system, enhance and improve regular supervision measures of food producers, explore supervision models for rural small-sized food production, processing and trading enterprises. Effectively stop the illegal uses of non-food raw materials, abuse of food additives and food production and trade by unlicensed enterprises. Strengthen supervision of food markets, regulate food advertising, especially advertising in small and medium-sized cities. Enhance supervision of rural food safety, direct the inspection and set up modern distribution and supervision network in rural areas, to comprehensively enhance the food safety assurance capability in rural areas.

### Column 9: Special Food Safety Activities

#### Special programs for food safety in rural areas

Strengthen special controls on pesticide and veterinary drug residues, abuse of prohibited drugs for animal and poultry products, and special controls of drug residue in aquatic products. Gradually establish a comprehensive supervisory network for rural food safety. Establish and popularize quality safety control system in small rural processing enterprises. Carry out special controls on urban-rural connecting food markets. Strengthen supervision and management of small rural restaurants and group dining places and establish reporting systems.

#### Special control of livestock slaughtering and processing enterprises

Severely crack down illegal slaughtering and set up guarantee system for harmless treatment of disease-affected meat.

#### Special control of high safety risk food processing industry

Set priorities every year to carry out comprehensive inspection and testing and implement

special controls on production and processing industry of high-risk foods.

#### **Administration of marking and labelling**

Strengthen administration of marking and labelling of food, food additives and food packaging materials.

#### **Safety assurance**

Implement food safety assurance projects for 2008 Beijing Olympics and 2010 Shanghai World Expo.

**Demonstration programs** Conduct special inspection on production and processing quality and set up model small enterprises and workshops. Launch self-discipline model food market, supply chains and meat producers. Establish "food safety supply chain demonstration programs", training programs for "hundred household safe meat demonstration factory", and "hundred household green food market".

### **10. Improve food safety accreditation**

Establish a unified "from field to table" national food accreditation system. Promote accreditation of organic and green foods, as well as non-polluted agricultural products and feed. Conduct accreditation of management of agricultural product makers and processing companies. Improve regulation in production, storage and transportation, and self-management of companies. Boost the mutual recognition of food accreditation system of China and the world.

### **11. Strengthen import-export food safety management**

Establish and improve quality safety access system of imported food and launch access procedures that are science based and in accordance with international practice. Manage imported food in categories based on risk assessment and improve the effectiveness of quarantine and inspection of imported food. Improve inspection system for imported food, especially inspection of pesticide, food additive, pathogenic micro-organisms, harmful and noxious substances and labelling. Establish and improve "one model, ten systems" food safety management system for export foods (i.e. "company + base + standardization" management model, and the ten registered management systems for growing and cultivating bases). Utilize to the most extent possible, the stipulations of the WTO "Agreement on Technical Barriers to Trade" and "Implementation of the Agreement on Sanitary and Phytosanitary Measures", establish a good food safety technical trade implementation system. Establish import-export food quality and safety control framework, establish and revise industry standards for inspection and quarantine relating to food safety testing.

#### **Column 10 Key Points for Import & Export Food Safety Administration**

##### **Improve import and export food safety quality administration system**

Carry out risk assessment, establish and improve inspection and quarantine access procedures for imported foods and market access requirements for all kinds of foodstuffs; implement import and export food quality safety monitoring plan. Establish epidemic, disease, pesticide and veterinary drug residue monitoring system for exported foods, and carry out electronic supervision on export food production and processing enterprises. Carry out export food quality traceability and recall systems, construct risk forecast and quick response systems and release red and black lists of import and export enterprises.

##### **Enhance technical assurance capability in import and export food inspection and quarantine**

Reinforce the import and export food testing capability and the building of expert team and

improve import and export food safety information system.
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## **12. Carry out advocacy, education and training on food safety**

Formulate the outline for food safety advocacy and education. Reinforce advocacy reporting on laws, regulations, policies and standards for food safety, popularize basic knowledge of food safety, enhance social awareness of food safety and strengthen consumer capabilities of self-protection, participation and surveillance. Accelerate the construction of food safety training system and hold food safety education and training programs of various forms and through various channels to government officials, law enforcers, enterprise managers and staff, journalists and consumers.

### **Column 11: Food Safety Advocacy, Education and Training**

#### **Food safety advocacy and education**

Conduct activities like "Bring food safety to the countryside", "Bring Food Safety to the Community" and "Bring Food Safety to the Campus". Develop the concept of "green consumption" and popularize education on food safety knowledge.

#### **Project on upgrading the qualities of food safety supervisors**

Carry out trainings on relevant food safety knowledge to law enforcers and professional technical personnel responsible for food safety supervision, raise their awareness of food safety knowledge and enhance their supervision capabilities.

#### **Project on upgrading the qualities of first-line responsible persons for food safety**

Strengthen training and education on legal representatives and managers of food production and business enterprises, raise their awareness of food safety knowledge and improve their food security assurance capability.

## **II Drug Safety**

### **13. Improve the level of drug safety supervision**

(1) Establish scientific drug assessment system.

Strengthen the construction of administrative regulations on drug registration and formulate the principles of guidance on drug research and technological development. Integrate administrative resources of drug registration, push forward the reform on drug registration and evaluation systems, control rigorously the registration and approval procedures for drugs and establish efficient turn-around and economical drug registration administrative system. Reinforce supervision and inspection on drug clinical research and the process prior to clinical practices and fully realize the conduct of drug non-clinical and clinical experiments under the supervision of Good Laboratory Practice (GLP) and Good Clinical Practice (GCP). Develop the research on drug evaluation technical methods, enhance and standardize safety evaluation techniques on innovative drugs and drugs imported into our country and encourage innovative drug research and development. Reinforce drug standards administration and implement "Activity Plan of Improving National Drug Standards". Establish the improved scientific assessment system of biotechnology products. Improve the national standards systems for pharmaceutical supplements and packaging materials and containers, which are in direct, contact with medicines. Establish an improved evaluation system of health food registration and inspection.

(2) Reinforce supervision on drug production quality.

Further improve the accreditation system of Good Drug Manufacture Practice (GDMP), revise the GDMP, enhance the implementation level of GDMP, and gradually meet the standards of GDMP in developed countries; strengthen dynamic supervision on pharmaceutical production,

ensure the quality of pharmaceutical production and promote the healthy development of pharmaceutical industry; push forward the implementation of Good Preparation Practice (GPP); strengthen supervision on the sources of Chinese medicines, improve the administrative system for Good Chinese Medicine Production Practice (GCMP), push forward the implementation of GCMP and ensure the production quality of Chinese herbal medicines; and strengthen supervision on pharmaceutical supplements and packaging materials and containers which are in direct contact with medicines.

(3) Improve the supervision system for drugs approved into the market  
Improve the monitoring network for adverse drug reaction, standardize adverse drug reaction and reporting monitoring systems, and strengthen the responsibilities of reporting adverse drug reaction. Formulate and implement Drug Re-evaluation Management Measures, put in place the supporting technical specifications and guidelines and carry out periodic and in batches the re-evaluation of drugs approved into the market. Establish and improve long-term risk management mechanisms on monitoring, early warning, emergency response, withdrawal from shelves and elimination of drugs approved into the market. Strengthen the construction of adverse drug reaction monitoring bodies, improve the monitoring system for adverse drug reactions, and enhance the adverse drug reaction monitoring capabilities at the city (prefecture) and county levels. Further improve the classification management system of prescription and non-prescription drugs, consistent with the medical system reform, fully implement the classification management of prescription and non-prescription drugs and push forward the legislation on the classification management of prescription and non-prescription drugs. Further standardize drug packaging and usage directions. Amend the accreditation standards of Good Supply Practice (GSP), improve the accreditation management measures of GSP and traceability system, formulate and implement Good Distribution Practice (GDP) and promote the development of modern logistics. Establish and improve drug abuse monitoring network and supervision network of special medicines and monitor the movement of each needle and each pill of special medicines. Establish monitoring reporting and early warning system for abuse and misuse accidents of narcotic drugs and psychotropic drugs, and improve the evaluation methodology and criteria of drug dependency and abuse potential of narcotic and psychotropic drugs.

(4) Improve the construction of drug testing system.  
Standardize the functions of drug testing agencies at all levels; rational allotment of drug testing resources; strengthen the studies on drug testing and inspection methods, establish technical platform for drug testing system and popularize rapid testing techniques; establish and improve information and data exchange systems of national drug testing techniques; improve drug testing system integrated with submission, sampling and approval, reform drug supervision sampling system and enhance the efficiency of the use of funds for drug sampling.

(5) Establish and improve Chinese medicine standards and technical evaluation system.  
Establish and improve Chinese medicine classification system and formulate management and technical evaluation criteria; construct the fundamental framework for Chinese medicine standards and technical evaluation system with Chinese characteristics and in conformity to the law of Chinese medicines, formulate and improve standards of Chinese herbal medicine, Chinese herbal medicine pills and Chinese traditional patent medicine, and establish the technical standards for Chinese herb germplasm collection and breeding, and appraisal technical specifications for characteristics of genuine traditional Chinese medicines; further improve the standards and specifications for the production and processing of Chinese medicine, Chinese herbal medicine pill and the procedure for Chinese formulated medicines; establish the quality assurance system for genuine traditional Chinese medicine; formulate technical evaluation standards before the Chinese medicine appear in the market and re-evaluation standards after the Chinese medicine appears in the market; formulate research

guiding principles of reference materials for Chinese medicines and establish Chinese medicine library for standard materials. Reinforce national support and supervision of national drugs. Actively advocate the establishment of international coordination mechanism for traditional medicines.

#### **Column 12: Drug Supervision and Control**

##### **Activity plan for upgrading the national drug standards**

Upgrade the standards of 4,000 varieties of Chinese traditional patent medicine, 500 varieties of chemical drugs and rectify the standards for 300 varieties of early stage new drugs, formulate standards of 223 varieties of common pharmaceutical supplements and complete formulation and revision of national standards for 1,000 Chinese herbs and 500 Chinese medicine pills.

##### **Key projects for drug re-evaluation after market entry**

Establish drug re-evaluation database and information exchange platform, provide safety information of drugs approved for the market, and conduct re-evaluation on key varieties like injection Chinese medicines.

##### **Projects for technology innovation and personnel training**

Promote technology innovation projects focused on studies of biotechnology products, Chinese medicine quality standardization, tissue engineering and stem cell medical products and quality control standards, new technologies and models of safety evaluation as well as the studies of testing technologies. Develop distance education system, carry out medical device management, technical and professional training, and complete demonstration training programs for leaders of pharmaceutical regulatory bodies at the provincial, city (prefecture) and county levels.

#### **14. Standardize safety supervision on medical devices.**

(1) Establish an improved medical device regulatory system.

Improve the regulatory system for medical device, timely amend Regulations for the Supervision and Administration of Medical Devices, formulate and implement Regulations for the Supervision and Administration of the Distribution of Medical Devices, formulate and revise the following regulations: Administration of Medical Devices Registration, Administration of the Registration of In Vitro Diagnostic Reagents, Administrative of Standards of Medical Devices, Classification Catalogue of Medical Devices, Stipulations on Medical Device Clinical Test, etc.

(2) Strengthen the construction of a medical device standards system.

Improve the medical device standards system, formulate and revise 500 national and industry standards, reinforce collaboration with international standardization organizations and enhance the adoption rate of international standards; and establish research and verification mechanism on medical device-related standard materials.

(3) Strengthen capacity building of medical device testing system.

Strengthen testing capacity building of national and provincial medical device. Make full use of societal resources and expand accreditation of testing agencies; improve the testing capacities for electrical safety, electromagnetic safety and bio-safety of medical devices; and strengthen the testing of high-risk medical devices. Establish working mechanism and system for the supervision of test sampling of medical devices and appraisal test sampling, expand testing items and scopes, standardize test sampling activities and strengthen test sampling efforts.

(4) Strengthen the construction of medical device appraisal and approval system.

Establish and improve national and provincial medical device technical appraisal system, establish teams of appraisal experts, and set up platform for the exchange and communication of medical device technology appraisal; establish and improve integrated technological appraisal standards; and standardize registration and approval procedures of medical devices. Improve medical device clinical test agencies, and carry out the qualification accreditation of clinical test agencies in line with the characteristics of medical devices profession. Establish clinical test appraisal and approval system for modern medical devices and high-risk medical devices.

(5) Strengthen quality control system of medical devices.

Formulate and implement step-by-step the general principles of quality control of medical devices and sterile medical devices, application guidelines of implantable medical devices, active medical devices, passive medical devices, active non-contact medical devices and in vitro diagnostic reagents and working guidelines for inspectors. Conduct quality management training programs on medical devices and strengthen the team building of inspectors. Gradually inspect the second and third category of medical device manufacturers on implementation of quality control system and urge the manufacturers to meet the requirements of the standards.

(6) Strengthen the construction of monitoring and re-evaluation system for adverse events of medical devices.

Formulate and implement Measures on Monitoring and Re-evaluation Management on Medical Device Adverse Events and Medical Device Recall Measures, formulate corresponding technical guidelines and standards, establish and improve the reporting system and strengthen the reporting responsibilities and obligations of the enterprises. Establish a technical platform for risk assessment of medical device approved for entry into the market, and establish early warning and recall systems.

(7) Strengthen supervision on the use of medical devices.

Reinforce research on the use of medical devices, and establish the supervision system on the use of medical devices. Strengthen technical research on medical device service life and product discard standards, establish supervisory evaluation methods for the use of medical devices, and enhance the efficiency of supervision on the use of medical devices.

### **Column 13: Supervision of Medical Device**

#### **Medical device standards**

The adoption rate of international standards is to reach 80%. Complete 200 standards for medical-use electric devices, 200 standards for medical-used passive products, 100 standards for diagnostic reagent products, accomplish the formulation and amendment of general safety standards for medical-use electric devices (the 2<sup>nd</sup> Version) and basic standards for electromagnetic compatibility.

#### **Project of Capacity Building of the Testing of Medical Devices**

Reinforce construction of national laboratory for biological functions of medical devices and improve medical devices testing system.

### **15. Strengthen supervision on pharmaceutical and medical devices market.**

(1) Severely crack down on making and selling of fake and shoddy medicines and medical devices. Focus on key investigations of major cases of making and selling fake and shoddy medicines and medical devices with extensive coverage, high-impact, and strong reaction by the public, any activity which constitutes a crime should be timely transferred to the judiciary to legally place the responsibility for the crime. Strengthen supervision on Chinese herbal



medicine market, Chinese herbal medicine and Chinese herbal medicine pills, and strongly rectify and standardize market order.

(2) Continue to rectify and standardize the advertisement of medicine and medical devices. Strengthen the building of qualities of people responsible for reviewing and approving advertisements. Review the contents of the advertisements strictly in accordance with relevant standards, establish an advertisement-monitoring network and intensify monitoring. Strengthen publicity of laws and regulations related to the advertisement of medicines and medical devices, increase the public's ability to distinguish unlawful advertisements and actively promote the effect of supervision by the society. Guide advertisers, advertising companies and advertisement disseminators to advertise in accordance with the laws, and block illegal advertising channels. Severely punish the manufacturers and traders of medicines and medical devices who seriously violate the laws. Gradually establish a comprehensive management and rectification system.

(3) Promote the building of a credibility system for medicines and medical devices. Improve credibility classification management of medicine, establish a integral credibility filing system from administration to people. Establish a credibility management system of medical device manufacturers, strengthen the construction of credibility evaluation quality system and credibility public information system, establish and improve the credibility monitoring files of medical device manufacturers and build medical device credibility operation mechanism. Establish "reputation files" for experts and departments involved in the evaluation of medicines and medical device products, approval of enterprises and accreditation inspection.

(4) Push forward the in-depth building of rural medicine supervision networks and supply networks. Collect experience in building rural medicine supervision networks and supply networks and establish a healthy operational mechanism. The building of rural medicine supervision networks and supply networks should be integrated with the construction of new socialist countryside, especially with that of new rural cooperative medical system. Formulate the guidance policy and supervision measures in accordance with the reality of rural medicine supply, encourage and guide the construction of medicine supply network in line with the development of modern logistics, support and provide guidance to self-collection, self-growing and self-application of Chinese herbal medicines by the rural basic medical institutes and ensure that farmers can access medicines safely, effectively, conveniently and timely.

#### **Column 14: Drug Safety Supervision in Rural Areas**

**Building Drug Supervision Network and Drug Supply Network in Rural Areas:** Guide, support and encourage legally operating drug enterprises to collect and supply to villages through the guidance of policies, to establish rural drug stores that are adapted to needs. Provide assistance to staff working on supervision and information, reinforce the drug supervision efforts in rural areas, disseminate basic drug use knowledge to farmers, establish "well functioning and effectively supervised" drug supervision networks and drug supply networks, to ensure drug use safety in rural areas through supervision efforts on various links from sources, through circulation to usage. To realize 100% coverage for drug supervision network, and 80% coverage for drug supply network.

#### **16. Re-enforce emergency response capacity building towards group accidents caused by drugs and medical devices.**

In order to accelerate the construction of monitoring and alert networks over unexpected group accidents associated with drugs and medical devices, so as to improve the



coordination and control as well as the rapid response capability in face of such accidents; to strengthen the emergency response capability of drugs and medical devices inspection institutions in key areas. To strengthen the efforts to render harmless fake drugs and medical devices according to the principle of "treatment on site or in close areas". To actively investigate a compensation system for harms caused by drugs.

#### **Column 15 Building of Emergency Response Capability for Drug and Medical Device Safety**

##### **Key Points for Building Emergency Response**

Reinforce the construction of national training and exercise bases for emergency response and treatment of drug and medical device accidents, improve the quality of emergency response teams, install equipment and apparatus necessary for emergency treatment, develop training courses on emergency response knowledge and capability and organize regular emergency response exercises, to enhance emergency treatment capability.

#### **17. Promote the Advance of Systematization of Drug and Medical Device Supervision Information**

To implement the "3511" Program, designed to promote inter-connection, communication and information sharing so as to attain the synergy amongst governmental departments and improve the efficiency and level of supervision. To accelerate the construction of various core business systems in drug and medical device registration, assessment, enterprise accreditation and verification, *inter-alia*. To expand and perfect the public service system, to accelerate the steps to open up the administration and supervision of drug and medical device, to continuously raise the level of services for enterprises and the general public.

#### **Column 16: Systematization of Drug and Medical Device Supervision Information**

The "3511" Program, on the basis of the existing integral administration network, is designed to establish and improve drug supervision information systems at national, provincial and municipal (regional) levels. To build on the basis of integrating existing resources, three information platforms (information infrastructure platform, information security platform and application supporting platform), five application systems (administrative access management system, integrated law enforcement administration system, rapid response system to major incidents, drug and medical device inspection and testing system and public service system), one center (Drug Supervision Information Resource Center) and one standard system (Construct a standardized system of State Food and Drug Administration information).

#### **18. Improve drug and medical device supervision infrastructure**

Overall plans must be worked out in order to improve working and equipment conditions by constructing office buildings and furnishing with necessary enforcement equipment within law enforcement institutions, so that in five years from now their office and enforcement equipment capacity will basically meet the demand arising from the enforcement activities, while regions economically more advanced are allowed to lead the move in an appropriate way. Integrate existing inspection and testing resources, establish reasonable schemes, improve experimental conditions, provide equipment and apparatus, to totally raise the hardware standard supported by high technology.

#### **Column 17: Infrastructure for Drug and Medical Device Supervision**

##### **Infrastructure construction program**

To aim at strengthening the building of infrastructure of enforcement units of local drug and medical device supervision authorities; to reform provincial and municipal drug inspection and testing institutions; and to provide them with basic equipment, facilities and apparatus for enforcement. Meanwhile, it is necessary to speed up the construction of the drug adverse reaction-monitoring network and implement the Project for the Relocation and Reconstruction of China Drug and Bio-products Assay Institute.

## **PART Four Assurance Measures**

### **I. Establish Scientifically Sound Concepts on Supervision and Renovate Supervision Institutes and Mechanisms**

According to the scientific concept of development and the specific requirements of institutional reform of the administration system of the state, actively probe, and renovate supervision institutions and mechanisms. With regard to food safety supervision, strengthen institutional construction, progress further to rationalize the responsibilities of relevant supervision departments, gradually establish a set of highly effective supervision institutes which are compatible with the requirements of scientific concept of development where responsibilities are clearly defined; avoid gaps in supervision; strengthen integrated law enforcement and combined law enforcement of related departments; actively probe, renovate and perfect the institutes of food safety supervision, gradually establish the lasting effective institutions for food safety supervision. On the aspect of drug supervision, institutional reform is to be advanced and the supervision mechanism to be improved by centralized decision-making, unified coordination and supervision exercised by administrative regions. Drug examination, approval and random inspection mechanism must be improved, the reform of administrative law enforcement system to be deepened so as to regulate enforcement activities of administrative laws, to renovate supervision mechanisms at various levels and to ensure enforcement can be well targeted. Problems newly found in the development should be properly handled and resolved, supervision capacity and capability must be enhanced.

### **II. Improve Safety Responsibility System, Reinforce Sense of Responsibility of Enterprises**

In accordance with the requirements of "the local governments take overall responsibilities, supervision departments shoulder their respective responsibilities and enterprises be the first responsible persons", food and drug safety responsibility systems should be established. Local governments are to strengthen organizing and leading efforts, periodically carry out analysis on local food and drug safety situation, establish supervision measures, reinforce supervision and inspection, and effectively handle food and drug safety incidents. All governmental departments are to collaborate and link up with each other to form a complete supervision chain. Production and marketing enterprises are to strengthen the awareness of self-discipline and fulfillment of responsibility, to build and complete corporate responsibility system and self-discipline system, to perfect internal management, enhance corporate credibility and to actively comply with and shoulder food and drug safety responsibility.

### **III. Complete Law and Regulatory System, Vigorously Promote Administration According to Law**

Advances in food sanitation law legislation and revisions should be attained in a timely manner, organizing efforts focused on implementing the Law of Agricultural Products Quality and Safety of the People's Republic of China should be carried out and the regulatory system related to food safety shall be established and perfected; Drug Administration Law of the People's Republic of China and the Rules for the Implementation of the Drug Administration Law of the People's Republic of China should be strictly complied with and a regulatory system related to food and drug safety shall be preliminarily put in place during the Eleventh Five Year Plan period. Deepen the reform of the administrative examination and approval

system, renovate the examination and approval methods, normalize examination and approval procedures, and advance the practice of making governmental affairs public. Establish public hearing and verification system for significant policy making in food and drug supervision, strengthen the administrative case review system. Renovate the mechanisms of supervision on administrative law enforcement, strengthen the supervision on the enforcement of administrative laws, establish and improve the responsibility tracking system, enhance the effectiveness on the supervision of the implementation of administrative laws. Enforce training activities on laws and regulations for grass root enforcement staff, in order to improve their overall quality and enforcement capability of administrative laws.

#### **IV. Increase Government Input, Provide Required Financial Assurance**

All levels of government must increase their input into all planned programs to which necessary support and financial assurance based on full utilization and reasonable allocation of existing resources shall be granted while taking into consideration specific situations of each case and following the principal of "being realistic and practical and behaving according to each one's own capabilities", so as to support food and drug safety infrastructure construction, improve food and drug safety supervision capabilities and ensure successful supervision enforcement.

#### **V. Promote the Effectiveness of Societal Supervision, Cultivate Favorable Atmosphere for Public Opinions**

Fully promote the effectiveness of the roles of food and drug related industry associations, institutes and intermediate organizations in credibility building, industry self-discipline as well as food and drug safety promotion. Encourage the establishment of various specialized food and drug safety organizations so as to fully make use of their advisory functions in the policy making process. Strengthen the publicity and dissemination of laws and regulations on food and drug safety, strengthen positive media reports on food and drug safety, timely publicize information on food and drug safety, guide public consumption choices, encourage media to supervise public opinions according to law, create favorable conditions for governmental supervision and regulation. Fully promote the effectiveness of consumer supervision, further improve the information collection channels of consumer complaints, build a system of supervision and regulation for market circulation with ample public participation, and complete the communication mechanism between government and consumers in the area of food and drug safety.

#### **VI. Strengthen the Exchange of International Cooperation, Accelerate the Raising of Supervision Level**

Through external exchanges and governmental cooperation, actively publicize the laws, regulations and policies for food and drug safety supervision of our country, to enlarge the international influence of our food and drug safety supervision, and to enhance our international standing in this field. Improve the professional quality and internationalization level of public servants through various means of exchange. Actively participate in related activities of the WTO, improve international food and drug safety cooperation and consultation mechanisms, maintain and develop cooperation and work exchange with relevant international organizations, food and drug safety supervision institutions of developed countries, study the advanced concepts and models of food and drug supervision, scientific standards system, advanced inspection and testing methods as well as safety management methods, so as to continuously improve our food and drug safety supervision level.

#### **VII. Establish Mechanism for the Implementation of the Plan, Ensure the Realization of the Planned Goals**

This plan is a guiding document for the work on food and drug safety supervision activities for the nation during the period of the 11th Five-Year Plan, the smooth implementation of

this plan will be a concrete demonstration for the proper execution of government responsibilities. The food and drug supervision departments are in charge of the overall coordination, individual related governmental departments are required to elaborate work plans for relevant areas within their respective responsibilities and organize their implementation. During the implementation of those plans, all relevant departments are to effectively strengthen their leadership, to be farsighted based on the current situation, to advance fully the supervision tasks, and to make key breakthroughs. Meanwhile, do well on the details of the work, analyze by item the work according to the goals of the plan, and match them closely with the corresponding annual work arrangement, propose the requirements, in order to carry out concrete implementations. Strengthen supervision, monitoring and evaluation, make timely suggestions for responsive adjustments to the plan, carry out linkage and supplementary work for the implementation of the plan, in order to ensure the due realization of the plan.

END TRANSLATION